# CLINICALTRIALS.GOV JHU RECORD REVIEW

| PROTOCOL ID | RECORD OWNER | REVIEWER | ❑ Registration<br>❑ Update status<br>❑ Results<br>*(add Results checklist)* | ❑ pACT/ACT<br>❑ Non-ACT |
|---|---|---|---|---|
| NCT# | | | | |

| DATE RELEASED | COMMENTS DATE | REPLY DATE | DATE PUBLISHED |
|---|---|---|---|
| | | | |

| GENERAL REVIEW ITEMS | NOTES |
|---|---|
| ❑ No monetary value (e.g. compensation, food voucher) entered anywhere in the protocol<br>❑ Record Owner is the PI (JHU Policy)<br>❑ PI on record matches IRB PI: _____<br>❑ Contact info for Record Owner is up-to-date<br>❑ NCT number included in IRB "Clinical Trials Information" section (if applicable)<br>❑ All Warnings (if needed)<br>❑ All parenthetical citations have been removed<br>❑ All acronyms have been expanded on their first use<br>❑ Spell-check complete<br>❑ Free-text fields are blank if there is no information to report, and do not contain text such as "TBD," "Pending," "N/A," "None" | |

## PROTOCOL SECTION

**STUDY IDENTIFICATION**

- ❑ Unique protocol ID is the IRB number (JHU Policy)
- ❑ Brief Title does not include study type (e.g., Phase I, Randomized…)
- ❑ Official title should match what is in the IRB (or grant application if applicable)
- ❑ Secondary IDs include NIH grant numbers (verify in IRB)

**STUDY STATUS**

- ❑ Record Verification Date is the current month/year
- ❑ Overall Status matches IRB/CRMS
- ❑ Study start date verified with CRMS enrollment date
- ❑ Completion Dates Actual/Anticipated have been evaluated for accuracy
- ❑ If timeframes for outcomes are the same the primary and study completion dates are identical

**SPONSOR/COLLABORATORS**

- ❑ Responsible Party: Sponsor (JHU Policy)
- ❑ All sources of support identified in IRB "Support Information" section included as Collaborators
- ❑ Full Name used and if not recognized, "Recognize" is selected

**OVERSIGHT**

- ❑ IND/IDE information completed (if applicable)
- ❑ Pending is not entered for IND/IDE number (if applicable)

**Verify Human Subjects Review**

- ❑ Board Status verified
- ❑ Approval Number is a valid IRB number
- ❑ Board Name: Johns Hopkins Medicine Institutional Review Board
- ❑ Board Affiliation: Johns Hopkins Medicine
- ❑ Phone: (410) 955-3008, Email: jhmeirb@jhmi.edu
- ❑ Address: 1620 McElderry Street, Reed Hall Suite B130, Baltimore, MD, 21205

**STUDY DESCRIPTION**

- ❑ Brief Summary does not unnecessarily duplicate information provided for other data elements
- ❑ Brief Summary clearly states the study's hypothesis or the purpose (for interventional and observational)
- ❑ Brief Summary and Detailed Description are written in complete sentences with no formatting errors
- ❑ Record does not use personal pronouns: "I, my, we, our, us" – becomes "the investigator(s)"; "you, your, they, them, their" – becomes "the participant(s)"

**CONDITIONS**

- ❑ Conditions/Focus of study are discrete and does not use verbs or complete sentences
- ❑ Keywords are not numbered or bulleted, each condition and keyword is listed individually, one per line

**STUDY DESIGN**

- ❑ All required fields are completed
- ❑ Verify Study Design based on protocol in IRB
- ❑ "Allocation" marked as "N/A" for single-arm interventional studies
- ❑ Enrollment number Actual/Anticipated verified

**ARMS/INTERVENTIONS**

- ❑ Arm Title or Group/Cohort Label is brief and informative (even if there is only 1 arm)
- ❑ Interventions and intervention descriptions are entered correctly (drug or device names should be added to title and description)
- ❑ Arms/interventions are cross-referenced appropriately

**OUTCOME MEASURES**

- ❑ Title is "outcome neutral", specific and states WHAT is being measured, only 1 variable must be assessed per outcome measure (unless it is a composite)
- ❑ Description explains WHAT is being measured, not WHY it is being measured
- ❑ Scoring scale name, score range, significance of upper and lower limits specified (if applicable)
- ❑ Unit of measure specified
- ❑ Time frame specified as a single time point or change between 2 time points (if unsure of duration, add up to the duration team is willing to follow each participant for that outcome measure e.g. "up to 1 year")
- ❑ Time points should be written in full e.g. 5 hours not 5hrs, 60 minutes not 60mins, 2 years not 2yrs
- ❑ Time frame should not be the whole duration of study if outcome measure specifies a duration for the assessment of that measure which is less than whole duration of study

  INCORRECT: "Safety and Toxicity", Description: "Safety of study drug."
  CORRECT: *"Safety as assessed by number of participants experiencing adverse events"* Description: *"Number of participants experiencing adverse events grade 3 or higher, as defined by Common Terminology Criteria for Adverse Events version 5.0 (CTCAE v5.0)"*

**ELIGIBILITY**

- ❑ Age Limits are consistent with the Eligibility Criteria and with other parts of the record
- ❑ Eligibility criteria is divided into Inclusion/Exclusion criteria in bulleted format

**CONTACTS/LOCATIONS**

- ❑ Central Contact Person specified and accurate (JHU Policy)
- ❑ Study Officials match IRB
- ❑ All study sites specified matches CRMS
- ❑ Recruiting status for each study site accurate (if at least one study site is recruiting then Study Status reflects "Recruiting")
- ❑ Each facility is listed in a separate field

**IPD Sharing Statement**

- ❑ The Plan to Share IPD is 'YES' or 'NO' (ICMJE does not accept 'UNDECIDED') if an option is selected.

**REFERENCES**

- ❑ Each citation is listed in a separate field (if applicable)

***Add results checklist if results entry submitted.***

**RESULTS SECTION**

**PARTICIPANT FLOW**

- ❑ Protocol Enrollment refers to total number of subjects who consented to protocol (including withdrawals after consent but not screen failures)
- ❑ Recruitment details (optional) explains any specifics used at time of recruitment
- ❑ Pre-assignment details explains (in detail) what happened to subjects who signed consent but were not assigned to an arm/intervention (e.g. withdrawals)
- ❑ Arms titles and arm descriptions specified consistent with protocol section
- ❑ Number of Participants Started refers to total number of participants assigned to each arm
- ❑ Number of Participants Completed refers to total number of participants who completed study intervention
- ❑ Reason(s) for Not Completed provided (optional)
- ❑ Divided into periods/milestones appropriately (if applicable)
- ❑ Total number of participants started cannot be greater than enrollment number
- ❑ Total number completed is equal to or less than "started"

**BASELINE CHARACTERISTICS**

- ❑ Overall Number of Baseline Participants should match Number of participants Started (from Participant Flow)
- ❑ Baseline Analysis Population Description explains if there is a discrepancy between Overall & Started numbers
- ❑ Arm titles/descriptions are consistent with participant flow and/or protocol section
- ❑ Data is presented per arm or all participants together for crossover design
- ❑ If "number of participants" is reported, make sure Measure Type is "Count of Participants"
- ❑ Baseline Measure Description is specified for all Study-specific measures

**OUTCOME MEASURES**

- ❑ Titles/descriptions/time frame meet the criteria (as specified on prior checklist)
- ❑ Results are reported per arm or by intervention for crossover design
- ❑ Analysis Population Description includes reason why Number of Participants analyzed is different than total number of participants that started or completed study from participant flow (if applicable)
- ❑ Type and Number of Units analyzed is indicated, if other than "number of participants" (e.g. Lesions)
- ❑ Unit of measure matches what is stated in Outcome Title/Description
- ❑ Sum of all results entered for each arm equals overall number of participants analyzed (if applicable)
- ❑ Verify true data is entered and there are no placeholders
- ❑ Time frame specified not more than duration of the study
- ❑ Statistical Analysis portion is optional (if entered, review for accuracy)

**ADVERSE EVENTS**

- ❑ Time frame specified
- ❑ Collection Approach specified
- ❑ Arm titles/descriptions consistent with other sections in the record
- ❑ Data presented per arm
- ❑ All-cause mortality specified (cross-check with number "not completed due to death" from participant flow and any mortality measures in outcome section, if applicable)
- ❑ Total Number "At Risk" must be equal to total number of participants who started the study

**LIMITATIONS AND CAVEATS**

- ❑ Information here is only about limitations, unvalidated data or any reason why data entered cannot be totally reliable and does not contain any discussion of results or any other information.

**CERTAIN AGREEMENTS**

- ❑ Principal Investigators are employed by the organization sponsoring the study

**RESULTS POINT OF CONTACT**

- ❑ Information is correct and valid email address/phone number entered

**DOCUMENT SECTION**

- ❑ Protocol (required for primary completion date on or after January 18, 2017)
- ❑ Statistical Plan (required for primary completion date on or after January 18, 2017)
- ❑ Informed Consent Form (required for studies approved on or after January 21, 2019)
- ❑ Cover Page
  - ❑ NCT Number
  - ❑ Study Title
  - ❑ PI Name (JHU-specific)
  - ❑ Date of Document (date document most recently updated or IRB approved, whichever is more recent)
- ❑ Additional Documents: _____
- ❑ Uploaded document(s) do not include a publication

**REFERENCES**

- ❑ Links to results verified as active (if applicable)

**Acronyms**

JHU – Johns Hopkins University

pACT – Probable Applicable Clinical Trial

ACT – Applicable Clinical Trial

PI – Principal Investigator

IRB – Institutional Review Board

NCT – National Clinical Trial

NIH – National Institutes of Health

CRMS – Clinical Research Management System

IND – Investigational New Drug

IDE – Investigational Device Exemption

ICMJE – International Committee of Medical Journal Editors